

08/719 742


**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/719,742	09/25/96	WILLIAMS	L 1172.003

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EXAMINER

LAZAR-WESLEY, E

ART UNIT

PAPER NUMBER

1812

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DATE MAILED: 12/01/97

 This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS
OFFICE ACTION SUMMARY
☒ Responsive to communication(s) filed on August 4, 1997
☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

 A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days; whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).
Disposition of Claims

- ☒ Claim(s) 1-51 is/are pending in the application.
- Of the above, claim(s) 16, 22, 24, 45-48 is/are withdrawn from consideration.
- ☒ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-15, 23, 25-44 and 49-51 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 586
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGE-

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DETAILED ACTION

1. The amendment filed August 4, 1997, has been entered.

Claims 1-15, 23, ²35-44 and 49-51 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13-15, 39-40 and 41-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite, because it is not clear if KGF should also be comprised in a pharmaceutical composition.

Claim 14 recites the limitation "the pharmaceutical composition KGF" in claim 13. There is no antecedent basis for this limitation in the claim.

Claim 14 is indefinite, because it is not clear if it is one pharmaceutical composition that contains both PDGF and KGF, or if PDGF and KGF are separately present in a same carrier or diluent.

Claims 39 and 40, and claims 41 and 42, are rejected as being duplicate claims.

The following is a quotation of the fourth paragraph of 35 U.S.C. § 112:

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Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claim 23 is rejected under 35 U.S.C. 112, fourth paragraph, for failing to further limit the subject matter of claim 1, because the patentable element of the kit is nothing but the pharmaceutical composition of claim 1. A kit must recite more than one element, and give the relationship between the elements. No weight is given to the printed matter.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-10, 12-15, 23, 25-26, 29-30, 33, 35, 37, 43, 49 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Yanni, US Patent No 5,624,893 (A) .

Yanni teaches compositions and methods for treating corneal haze due for example to scar formation (col.7, lines 42-47) or altered wound healing (col.8, lines 52-56). These compositions comprise wound healing modulators including growth factors such as PDGF-BB, PDGF-AA, PDGF-AB, KGF, IGF-I and IGF-II (col.7, lines 42-47). The factors can be isolated from mammalian cell types or can be produced by genetically engineered microorganisms such as bacteria and yeasts (col.5, lines 46-52). The individual wound healing modulators or combinations thereof can be applied

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uniquely or sequentially. They can be applied topically, in various forms, like solutions, gels, or via a solid matrix (col.11, lines 1-20).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yanni(A) in view of Danilenko et al., American Journal of Pathology 147(5):1261-77(U), November 1995 and Lynch et al. PNAS 84:7696-7700, November 1987(V).

The claim is to a method of repairing skin.

Yanni teaches a method of treating of scar formation and of altered wound healing of lesions in the cornea, using PDGF, KGF and IGF as discussed above. He does not specifically teach repair of skin.

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Danilenko et al teach a method for repairing skin, where the combination of PDGF and KGF induces production of both granulation tissue/extracellular matrix and new epithelium (page 1267, col.2 and Figure 3). He suggests strategies including additional combinations of recombinant growth factors being useful for significant acceleration of wound repair (top of page 1273 and page 1274, last paragraph).

Lynch et al. teach a method for wound healing using a combination of IGF-I and PDGF (page 7700, col.2).

It would have been obvious for one of skill in the art at the time of the invention to combine PDGF, IGF and KGF as taught by Yanni for the cornea, in order to repair skin, because the combinations of PDGF and KGF or PDGF and IGF have been taught by Danilenko and Lynch to be effective, and because of Danilenko's suggestion to use additional combinations of growth factors to promote wound repair. One would have been motivated to do so for therapeutic purposes, and one would have had reasonable expectation of success because of Yanni's teachings.

7. Claims 27, 28, 31, 32, 34, 36, 38-42, 44 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanni et al. (A), Danilenko et al., American Journal of Pathology 147(5):1261-77(U), November 1995 and Lynch et al. PNAS 84:7696-7700, November 1987(V) as applied to claims 1-15, 23, 25-26, 29-30, 33, 35, 37, 43, 49 and 51 above, and further in view of Jyung et al., Surgery 115(2):233-9, February 1994 (W).

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The claims are to pharmaceutical compositions and methods for repair of epithelial tissues and skin comprising PDGF, KGF, IGF and IGFBP.

The teachings of Yanni et al.(A), Danilenko et al.(U), and Lynch et al.(V) are discussed above. They do not teach the use of IGFBP.

Jyung et al.(W) teach that the combination of IGF-I with IGFBP-I has a potent effect on wound healing in rats (Table 1).

It would have been obvious for one of skill in the art at the time of the invention to add IGFBP to the combination of PDGF, KGF, and IGF taught to be useful in wound repair, because of Jyung teachings that IGFBP potentiates the wound healing effect of IGF. One would have been motivated to do so, in order to increase wound healing.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957.

Official papers filed by fax should be directed to (703) 308 4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [stephen.walsh@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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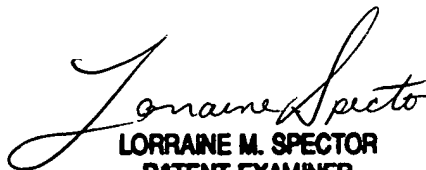
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

November 21, 1997

EW


LORRAINE M. SPECTOR
PATENT EXAMINER
GROUP 1800